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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/759,892 | 01/16/2004 | Mary Aldritt | 208-022US1 | 8476 |

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| EXAMINER | |
|---|---|
| HOFFMAN, SUSAN COE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/759,892 | ALDRITT ET AL. | |
| | Examiner | Art Unit | |
| | Susan Coe Hoffman | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *20-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/05; 1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment filed July 11, 2006 has been received and entered.

2. Claims 1-30 are currently pending.

### *Election/Restrictions*

3. Applicant's election of Group I, claims 1-19 in the reply filed on July 11, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claim 20-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2006.

5. Claims 1-19 are examined on the merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 15, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 12 is indefinite because it is unclear if the composition further comprises sorbitol or if the sorbitol is intended to function as the lubricant or binder in the tablet composition.

7. Claim 13 is indefinite because it is unclear what amounts of water are encompassed by "excess water."

8. Claim 15 is indefinite because the phrase "cranberry flavoring agent" is confusing. It is unclear if the flavoring agent is cranberry flavored or if it is an agent that flavors the cranberry, i.e. sugar or another type of sweetener. Thus use of the language "cranberry flavoring agent" is considered to encompass the use of an agent that provides flavoring to the cranberry extract.

9. Claims 17 and 18 are indefinite because it is unclear what amounts of decrease in bacteria amounts are encompassed by a "measurable decrease."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 3-10, 13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,299,925.

US '925 teaches a water soluble effervescent formulation that contains a carbonate salt, an acid, a lubricant, a binding agent and a flavorant (see claim 1). The reference also specifically claims including 5 to 50% of a fruit extract which can be cranberry (see claim 23). In addition, the reference specifically claims using citric acid as the acid in the formulation and sodium bicarbonate as the carbonate salt (the base) (see claims 27 and 28). The reference also claims using sodium benzoate and polyethylene glycol as the lubricant (see claim 30). The formulation is claimed to be a tablet (see claim 35).

The reference does not specifically teach that the effervescent tablet has the same amounts of cranberry as claimed or that the tablet has the same physical characteristics such as the hardness and water solubility claimed. The amount of a specific ingredient in a composition and the physical characteristics of the tablet are clearly result effective parameters that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount and physical characteristics would have been obvious at the time of applicant's invention.

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would intrinsically have to have the same effects if applicant's invention functions as claimed.

11. Claims 11, 12, 14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,299,925 as applied to claims 1, 3-10, 13, and 15-18 above, and further in view of US Pat. Pub. No. 2003/0161875.

The teachings of US '925 are discussed above. The reference does not specifically teach using sorbitol or magnesium hydroxide in the effervescent tablet formulation. US '875 teaches using sorbitol and magnesium hydroxide as fillers in effervescent tablets. The reference teaches using these ingredient interchangeably with many of the same ingredients used in the tablet taught by US '925 (see paragraph 24 of '875 and paragraphs spanning columns 4 and 5 of US '925). Thus, the use of sorbitol and magnesium hydroxide in effervescent tablet was known in the art at the time of the invention. An artisan of ordinary skill would reasonably expect that sorbitol and magnesium hydroxide could be used to formulate the tablet taught by US '925 based on their functional equivalence with ingredients. This reasonable expectation of success would motivate the person of ordinary skill in the art to modify the tablet of US '925 to include sorbitol and magnesium hydroxide.

12. Claims 1-10, 13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,231,866 in view of US Pat. No. 6,299,925.

US '866 teaches an extract from cranberry made using juice and oils extracted from cranberry fruits and seeds (see column 3, line 56-column 4, line 8). The extracts contains

proanthocyanins (see column 3, lines 22-28). The extracts are formulated into tablets and are used to treat urinary tract difficulties (see column 8, line 1 and example 7). Dosages of 50 to 5000 mg are included in the formulations (see claims 10-12). Thus, the reference teaches a tablet containing the claimed dosages of cranberry extract; however, the reference does not specifically teach using an effervescent tablet.

US '925 teaches an effervescent tablet as discussed above in paragraph 10. The tablet is specifically claimed to contain a carbonate salt, an acid, a lubricant, a binding agent and a flavorant (see claim 1). The reference also specifically claims including 5 to 50% of a fruit extract which can be cranberry (see claim 23). In addition, the reference specifically claims using citric acid as the acid in the formulation and sodium bicarbonate as the carbonate salt (the base) (see claims 27 and 28). The reference also claims using sodium benzoate and polyethylene glycol as the lubricant (see claim 30). The reference teaches that the use of this effervescent tablet to administer pharmaceutical agents is superior to other types of administration because the use of the effervescence greatly increases the bioavailability of the active ingredients which allows for an increased medicinal benefit. In addition, the reference teaches that the effervescent tablet is superior in its ease in use and transport (see column 4 lines 6-40). Based on these benefits, an artisan of ordinary skill would reasonably expect that the tableted cranberry extract of US '866 could be improved by using the effervescent tablet taught by US '925. This is especially true in light of the teaching by US '925 that cranberry compositions are known to have limited bioavailability (see column 2, lines 8-11). This reasonable expectation of successful results would motivate the artisan of ordinary skill to modify the cranberry extract tablet of US '866 to create an effervescent tablet as taught by US '925.

The references do not specifically teach adding the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

13. Claims 11, 12, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,231,866 and US Pat. No. 6,299,925 as applied to claims 1-10, 13, and 15-18 above, and further in view of US Pat. Pub. No. 2003/0161875.

The teachings of US '866 and US '925 are discussed above. Neither reference specifically teaches using sorbitol or magnesium hydroxide in the effervescent tablet formulation. US '875 teaches using sorbitol and magnesium hydroxide as fillers in effervescent tablets. The reference teaches using these ingredient interchangeably with many of the same ingredients used in the tablet taught by US '925 (see paragraph 24 of '875 and paragraphs spanning columns 4 and 5 of US '925). Thus, the use of sorbitol and magnesium hydroxide in effervescent tablet was known in the art at the time of the invention. An artisan of ordinary skill would reasonably expect that sorbitol and magnesium hydroxide could be used to formulate the

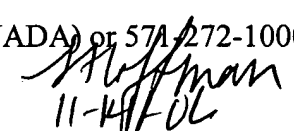
tablet taught by US '925 based on their functional equivalence with ingredients. This reasonable expectation of success would motivate the person of ordinary skill in the art to modify the tablet of US '925 to include sorbitol and magnesium hydroxide.

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Susan Coe Hoffman
Primary Examiner
Art Unit 1655